

## Medicament Carrier

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*insert*      *a*

The present invention relates to a carrier for containment of a product. In particular, it relates to a medicament carrier for incorporation into an inhalation device to enable administration of medicament to a patient.

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Individual carriers or blister packs are widely used across many different industries to package, present and deliver products to customers, users and patients. Thus, for instance, blister packs containing unit quantities of food, toiletries, cosmetics, electrical and photographic products are commonly sold in  
15 supermarkets. These packs are generally designed to provide a clean, durable, moisture-free environment to protect and present products while at the same time offering easy accessibility for the consumer at low cost. Blister packs are particularly suitable for use within the pharmaceutical and health care industries.

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Inhalation devices are known for use with blister packs in which the medicament is held in powder form in the blisters thereof. Such packs are typically comprised of two separate entities, one of which is suitably formed to define the medicament retainer and the other is hermetically sealed to the first to form the medicament carrier. It is an object of the present invention to provide a  
25 medicament carrier wherein the carrier comprises a single sheet or elongate strip thus providing significant advantages over the prior art in that the strip is straightforward to manufacture, providing both ease of use and reduction in manufacturing costs.

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Known drug delivery systems including blister packs generally include a puncturing member, which punctures each blister in turn thus enabling the medicament to be inhaled therefrom. Generally release of the medicament dose is by puncture or rupture of the second entity. Such packs suffer from the disadvantage that they may be difficult to use, particularly as the dose releasing  
35 means may comprise one or more elongate members, such as cords or tapes,

which are separately attached to films used to seal the medicament retainers. The present invention in embodiments provides advantages over such packs in that it is especially useful for the elderly and infirm since the free end of the strip is readily identifiable and simple to grasp, without the added complication of numerous cords or tapes which act as a separate release mechanism.

It will also be seen that in several embodiments of the present invention the free end of the sheet or strip is peeled back automatically by virtue of a releasing means incorporated into the inhalation device, hence avoiding the need to grasp the strip manually. Such a feature further enhances the ease of use of the inhalation device since minimum force is required by the user to peel back the medicament retainer.

It is also an object of the present invention to provide a medicament carrier for use in combination with an inhalation device, wherein the design of the inhalation device has the potential, if desired, to handle a medicament carrier having a large number of discrete unit doses without the device becoming unacceptably large. Thus, although a single use inhaler is referred to in the drawings/illustrations, it is possible that such an inhaler may be easily adapted to accommodate a multi-dose medicament container.

It is a further object of the present invention to provide a carrier for a wide range of different product types, comprising a single sheet or elongate strip, which is easy to use and of low manufacturing cost.

25 *insert a2* According to one aspect of the present invention there is provided a carrier comprising a sheet having a first portion and a second portion; a retainer in the first portion for containment of product; a fold in the second portion such that the second portion is foldable towards the retainer to form a cover therefor; and a join between the cover and the retainer.

30 *insert a3* Preferably the sheet comprises an elongate strip. More preferably the retainer comprises a pocket or a hole.

In another aspect of the invention there is provided a carrier comprising a plurality of retainers in the first portion, wherein the second portion is foldable towards the plurality of retainers to form a cover therefor; and a join between the cover and the plurality of retainers.

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In a further aspect of the invention there is provided a carrier additionally comprising a fold in the first portion such that the first portion is foldable towards the retainer to form a base therefor; and a join between the base and the retainer.

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In one aspect of the invention there is provided a carrier additionally comprising an inert support within the retainer for bearing product thereon. Typically this support comprises a grid, mesh, sponge or disc to which product is entrapped, absorbed or adsorbed.

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In another aspect of the invention there is provided a carrier comprising a second fold in the second portion to form a pull release tab.

Preferably, the pull release tab is shaped for ease of grip.

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Preferably, the pull release tab has a looped end enabling it to be connected to a release mechanism incorporated within a device, such as an inhalation device, or for receipt of finger in manual release.

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Preferably, the pull release tab has at least one perforation therein allowing it to be easily grasped by the user or otherwise allowing it to be connected to a release mechanism incorporated within a device such as an inhalation device.

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In another aspect of the invention there is provided a carrier in multi-unit form comprising a series arrangement of a plurality of carriers as described above.

Preferably, each of the plurality of carriers is connected together.

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More preferably, each of the plurality of carriers is formable from the same sheet or elongate strip.

In one aspect, the sheet or elongate strip has a point of weakness between each carrier in the series arrangement, thereby enabling separation of individual carriers from the sheet or elongate strip.

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Preferably, the sheet or elongate strip is flexible to enable it to be formed for example, into a spiral, helical or zig-zag shape for incorporation into a suitable device, such as an inhalation device. More preferably, the sheet or elongate strip comprises material selected from the group consisting of metal foil, an organic polymeric material and paper. Most preferably, the carrier comprises a laminate.

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Preferably, the join is formable by a joining method selected from the group consisting of heat, laser, radio frequency, adhesive, staple, stamp, pressure and ultrasonic sealing.

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Preferably, the join is peelable to enable peelable access to the retainer.

*presented*  
20 *by* Preferably, the retainer ~~is shaped~~ for receipt by a holder.

In a further aspect, there is provided a carrier comprising a medicament therein. Preferably the medicament is in dry powder, tablet, liquid, paste, cream or capsular form. More preferably the medicament is selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof.

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According to another aspect of the present invention, there is provided an inhalation device comprising a housing in combination with a medicament carrier as described above. Preferably the housing includes a holder for receipt of the retainer of the carrier. More preferably the inhalation comprises a pull release tab and the pull release tab protrudes from the housing.

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Preferably the inhalation device comprises a release mechanism and the pull release tab connects to the release mechanism. More preferably, the release mechanism is separable from the housing of the inhalation device.

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According to another aspect of the present invention, there is provided a method of making a carrier comprising forming a retainer in a first portion of a sheet or elongate strip; filling the retainer with product; folding a second portion of the sheet or elongate strip towards the retainer to form a cover therefor; and forming a join between the cover and the retainer.

10 In one aspect, there is provided a method comprising forming a plurality of retainers in a portion of a sheet or elongate strip; filling the plurality of retainers with product; folding a second portion of the sheet or elongate strip towards the plurality of retainers to form a cover therefor; and forming a join between the  
15 cover and the plurality of retainers.

20 In an other aspect, there is provided a method of making a carrier as described above additionally comprising a fold in the first portion such that the first portion is foldable towards the retainer to form a base therefor; and a join between the base and the retainer.

25 Preferably there is provided a method of making a carrier in multi-unit form comprising successive iterations of the method described above to form a series arrangement of a plurality of carriers.

According to another aspect of the present invention, there is provided a method of opening a carrier as described above comprising pulling the pull release tab in order to enable access to the retainer.

30 In a further aspect of the present invention, there is provided the use of a carrier, as described above, for dispensing medicament.

In a preferred aspect, the medicament is used in the treatment of respiratory disorders. More preferably the medicament is used in the treatment of asthma.

35 Most preferably the medicament is salbutamol or albuterol.

In one aspect, there is provided a carrier comprising an electronic component therein. Preferably the electronic component is selected from the group consisting of semi-conductor, integrated circuit chip, fuse and battery.

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In another aspect, there is provided a carrier comprising a food therein. Preferably the food is selected from the group consisting of meat, mycoprotein, milk, cheese, flour, pasta, rice, oil, sugar, confectionery, vegetable, herbal, snack, convenience and fruit foodstuffs.

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In a further aspect, there is provided a carrier comprising a beverage therein. Preferably the beverage is selected from the group consisting of water, milk, coffee, cocoa, tea, fruit, carbonated and alcoholic drinks.

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In one aspect, there is provided a carrier comprising a toiletry therein. Preferably the toiletry is selected from the group consisting of toothpaste, soap, mouthwash, shampoo, skin and face cream.

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In another aspect, there is provided a carrier comprising a cleanser therein. Preferably the cleanser is selected from the group consisting of soap, detergent, enzymic preparation and organic solvent.

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In a further aspect, there is provided a carrier comprising a disinfectant therein. Preferably the disinfectant is selected from the group consisting of sterilant, antiseptic and bleach.

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In another aspect, there is provided a carrier comprising a light-sensitive material therein. Preferably the light-sensitive material comprises a photographic film.

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In yet another aspect, there is provided a carrier comprising a marking material therein. Preferably the marking material is selected from the group consisting of toner, ink, dye, pigment, acid and alkali.

In one aspect, there is provided a carrier comprising a covering material therein. Preferably the covering material is selected from the group consisting of paint,

pigment, dye, corrosion inhibitor, electrical conductor, electrical insulator and static inhibitor.

In a further aspect, there is provided a carrier comprising a toy therein.

- 5 Preferably the toy is selected from the group consisting of model, figure, doll, animal, jigsaw and game.

In another aspect, there is provided a carrier comprising haberdashery therein.

- 10 Preferably the haberdashery is selected from the group consisting of button, bobbin, needle, pin, eye, hook and fastener.

In one aspect, there is provided a carrier comprising a tool therein. Preferably the tool comprises a domestic tool. More preferably, the domestic tool is selected from the group consisting of can opener, bottle opener, ring-pull  
15 opener, scissors, knife, fork and spoon.

Optionally the tool comprises a home maintenance tool. Preferably the home maintenance tool is selected from the group consisting of nail, screw, pin, wire, screwdriver, knife, brush, spanner, ruler and marker.

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In another aspect, there is provided a carrier comprising stationery therein. Preferably the stationery is selected from the group consisting of pencil, pen, ruler, crayon, eraser, marker, stencil, protractor, compass and paper.

- 25 In a further aspect, there is provided a carrier comprising an adhesive therein. Preferably the adhesive bonds materials selected from the group consisting of paper, plastic, wood, rubber, glass and metal.

- 30 In one aspect, there is provided a carrier comprising an agrochemical therein. Preferably the agrochemical is selected from the group consisting of herbicide, insecticide, fungicide, rodenticide, nematocide, acaricide and plant growth regulator.

In another aspect, there is provided a carrier comprising a plant seed therein. Preferably the seed is derived from plants selected from the group consisting of monocotyledonous and dicotyledonous plants.

5 In a further aspect, there is provided a carrier comprising a contraceptive therein. Preferably the contraceptive is either a contraceptive device or a contraceptive drug. Preferably the contraceptive device is selected from the group consisting of condom, diaphragm, sponge and coil. Preferably the contraceptive drug is  
10 selected from the group consisting of spermicide, estrogen, ethinyl estradiol, progesterone, levonorgestrel and norgestrel.

In one aspect, there is provided a carrier comprising a medical instrument therein. Preferably the medical instrument is selected from the group consisting of scalpel, thermometer and syringe.

15 In another aspect, there is provided a carrier comprising laboratory equipment therein. Preferably the equipment is selected from the group consisting of dispenser tip, microbial filter, filter paper, aseptic container, petri-plate, vial, test tube, tissue-culture vessel and pipette.

20 In a further aspect, there is provided a carrier comprising a catemenial product therein. Preferably the catemenial product comprises a tampon.

In another aspect, there is provided a carrier comprising nicotine therein.

25 Preferred embodiments of the medicament carrier according to the present invention will now be described with reference to the accompanying drawings in which:

30 Fig. 1a is a cross-sectional perspective sideview of a first medicament carrier in accordance with the present invention in the closed configuration.

Fig. 1b is a cross-sectional perspective sideview of the first medicament carrier in accordance with the present invention in the open configuration.

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Figure 1c is a perspective sideview of a second medicament carrier in accordance with the present invention in the open and closed configuration.

5 Figure 1d is a perspective sideview of a third medicament carrier in accordance with the present invention in the open and closed configuration.

Fig. 2 is a perspective sideview of a fourth medicament carrier in a multi-dose form.

10 Fig. 3a is a perspective sideview of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1.

15 Fig. 3b is a cross-sectional front view of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the mouthpiece is in the closed configuration.

20 Fig. 3c is a cross-sectional front view of the inhalation device of Figure 3b, wherein the carrier is in the open configuration.

Fig. 4a is a perspective view of an inhalation device comprising a medicament carrier in accord with the present invention.

25 Fig. 4b is a cross-sectional front view of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the mouthpiece is in the closed configuration.

30 Fig. 5a is a perspective sideview of part of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1.

35 Fig. 5b is a cross-sectional sideview of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the carrier is in the closed configuration.

Fig. 5c is a cross-sectional sideview of the inhalation device of Figure 5b, wherein the carrier is in the open configuration.

Fig. 6a is a cross-sectional sideview of the insert of an inhalation device incorporating a medicament carrier, which is a variation of that shown in Figure 1, wherein the carrier is in the closed configuration.

Fig. 6b is a cross-sectional sideview of the insert of Figure 6a, wherein the carrier is in the open configuration.

Figure 1a shows a medicament carrier in the closed configuration comprising an elongate strip 10, whose first portion contains a blister 20 suitable for containing a powdered medicament. A second portion of the elongate strip is folded over once to form a cover for the blister 20 and folded a second time to define a pull release tab 30. The contents of the blister 20 are exposed by pulling the pull release tab 30 in a horizontal direction relative to the medicament retainer, either manually or by a release mechanism, to break the seal 25 around the periphery of the blister 20, so that the medicament carrier is then in the open configuration as shown in Figure 1b.

Figure 1b shows the medicament carrier of Figure 1a in the open configuration wherein the pull release tab 30 has been sufficiently peeled in order to break seal 25 around the periphery of the blister 20 thereby removing the cover portion and exposing the medicament contained therein.

Figure 1c shows a second embodiment of a medicament carrier according to the present invention. Elongate strip 10 has a series of retainers 21 each comprising a mesh which itself comprises a plurality of holes for containment of medicament. The first portion of elongate strip 10 is folded toward mesh 21 to form a base therefor, while the second portion is folded (in the direction shown by the arrows) to form a cover for mesh 21. On folding, seals 25 are formed around the periphery of mesh 21 between the cover (not shown) and base sheets. Medicament may be released from mesh 21 by pulling on tab 30 to break seal 25. The mesh 21 may in embodiments be substituted by a pocket for containment of medicament.

Figure 1d shows a medicament carrier comprising a plurality of mesh retainers 21 in the open and closed configuration. The first portion of elongate strip 10 is folded toward retainer 21 to form a cover sheet while the second portion is folded in the opposite direction to form a base (as shown by the arrows). Seals 25 are formed around retainer 21 between the cover and base sheets. A hole 16 in the base sheet secures the medicament carrier within an inhalation device (not shown) while corresponding hole 15 engages an opening mechanism in the device. The medicament carrier is opened by gripping tab 30 directly, or by engaging hole 30, and pulling in an anti-clockwise manner.

Figure 2 shows a combination of Figures 1a and 1b in both the open and closed configurations in which the medicament carrier is in a multi-dose form. The multi-dose medicament carrier is formed from an elongate strip incorporating a number of first portions each containing a blister 120. A corresponding second portion is folded over once as described above in order to define a cover for said blister 120 and folded a second time to form a pull release tab 130 with which to break the seal 125 and expose the medicament contained within the blister.

Figure 3a shows the insert of a first inhalation device designed to accommodate the medicament carrier of the present invention. The insert comprises a separate housing 240 and a flexible ring 250 which slots into said housing. The ring 250 has at least one notch 260 at a suitable point on the circumference. The blister 220 (shown in the open configuration for exemplification only) sits in the closed configuration in support 242 within the inhalation device and the looped pull release tab 230 engages with the notch 260 to form a release mechanism for opening the cover of the blister. Actuation of the release mechanism is achieved by the user gripping the ring and pulling it in a downwards motion, whereby the pull release tab 230 is automatically peeled backwards to expose the contents of the blister 220.

Figures 3b and 3c show a first inhalation device comprising the insert described in Figure 3a in the open and closed positions respectively. The medicament carrier of the present invention is housed in a recess 270 and connected to the ring 250 by the pull release tab 230 as described in Figure 3a above. In the

storage position (Figure 3b) the circumference of the ring 250 seals the mouthpiece 280 and actuation of the device from this position to the in-use position (Figure 3c) is achieved by a two-handed operation. In practice, this may be achieved by holding the body 290 of the device between thumb and forefinger and pulling the ring 250 in a downward motion as described in Figure 3a. It will be seen that this action causes the pull release tab 230 to be peeled backwards and the contents of the blister 220 to be exposed. Complete removal of the ring 250 from the body of the device 290 uncovers both the mouthpiece 280 and an airway 295 at the side of the device, enabling the blister contents to be inhaled through the mouthpiece 280.

Figures 4a and 4b show a second inhalation device comprising a similar insert to that described in Figure 3a. Figure 4a shows an inhalation device wherein the pull release tab 330 protrudes from the housing in order to be freely pulled by the patient. Actuation of the device is similar to that of the device in Figures 3b and 3c. This is achieved by pulling the pull release tab 330 as before (Figure 4a) and rotating a rigid ring 350 (Figure 4b) in order to uncover the mouthpiece 380 and airway 395 to allow the contents of the blister to be exposed.

Figure 5a shows part of the insert of an inhalation device encompassing a medicament carrier which is a variation of that shown in Figure 1a wherein the looped pull release tab 430 is attached to a notch 460 in the insert to provide a release mechanism. Ports 461 enable air flow through the inhalation device when in use.

Figures 5b and 5c show a third inhalation device for use with the insert of Figure 5a. The device comprises a tubular-shaped body 405 into which position 420 a blister is located when attached to an insert similar to that described in Figure 5a. The inhalation device has a mouthpiece 480 and a slidably movable projection 425. In the storage position (Figure 5b) the projection 425 is located close to the mouthpiece 480 so that both the mouthpiece and the airway 435 are covered. Actuation of the device from this position to the in-use position (Figure 5c) is achieved by sliding the projection 425 translationally to the forward locked position, thereby pulling tab 430 and exposing medicament within blister 420 for release. On inhalation by the patient through the mouthpiece 480, air is drawn

through airway 435 and then through passage 433 to the blister 420 wherein medicament is drawn out of the blister 420 through passage 434 and thence to the mouthpiece 480.

5        Figures 6a and 6b show a fourth inhalation device incorporating a medicament carrier which is a variation of that in Figure 1a in the open and closed positions, respectively. Figure 6a shows that when the air flows towards the sealing flap 555 in the direction shown, the contact between the sealing flap 555 and the edge of the blister 520 is not broken. Such airflow would be created by  
10        exhalation. When the free end of the strip 530 is pulled to expose the contents of the blister 520 and the direction of airflow reversed by inhalation, as shown on Figure 6b, then the sealing flap 555 is opened and the medicament present in the blister 520 is entrained in the airflow and carried through the device to be administered to the patient.

15        Standard methods of filling and sealing the medicament container may be used and form another aspect of the present invention. Such methods include entering a hollow, or a number of hollow, pin into a powder bed so that a defined quantity of powder is taken up into the or each pin. The pin, or number of pins,  
20        is then positioned above the individual medicament containers and the powder contained therein released by means of a piston. On removal of the pin, or pins, the medicament containers are sealed so that the powder is contained in a medicament container defined by the two portions of the elongate strip.

25        Suitable methods of sealing the medicament carrier include the use of adhesives, staples, stamps, pressure and welding methods selected from hot metal welding, radio frequency welding, laser welding and ultrasonic welding. Such sealing techniques may be used to form a suitable join around the periphery of the retainer which is capable of being peeled away by the patient or  
30        by a suitable release mechanism in a controlled manner when in use. The release mechanism may be designed to confer a mechanical advantage, thereby reducing the operating force required to break the seal.

35        Although not directly relevant to the present invention, it should be noted that medicaments suitable for administration by an inhalation device using the

present invention are any drug particles suitable for delivery to the bronchial or alveolar region of the lung which have an aerodynamic diameter of less than 10 micrometers. Larger particles may be used if delivery to other portions of the respiratory tract is desired, such as the mouth or throat. Such medicaments may  
5 be selected from a wide range of powdered medicaments and may be in amorphous or crystalline form and may have been comminuted, e.g. ground, and, if necessary, classified and sieved, e.g. on an air jet sieve, to obtain a suitable size or may have been made by direct crystallisation to the desired size.

10 The medicament carrier herein is suitable for containing medicament, such as those for the treatment of ulcers, e.g., omeprazole, lansoprazole, lipid levels, e.g., simvastatin, atorvastatin, hypertension, e.g., amlodipine, depression, e.g. fluoxetine, paroxetine, sertraline, allergies, e.g., loratidine, and psychosis, e.g., olanzapine.

15 In particular, the medicament carrier is suitable for containing medicament for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem;  
20 antiallergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatory, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate, ciclesonide or triamcinolone acetate;  
25 antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; diuretics,  
30 e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in  
35 the art that, where appropriate, the medicaments may be used in the form of

salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament and/or to minimise the solubility of the medicament in the propellant.

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Preferred medicaments are selected from albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclometasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

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Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate). A

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particularly preferred combination comprises salmeterol xinafoate salt and fluticasone propionate.

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It may be appreciated that any of the parts of the medicament carrier which contact the medicament may be coated with materials such as fluoropolymer materials which reduce the tendency of medicament to adhere thereto. Suitable fluoropolymers include polytetrafluoroethylene (PTFE) and fluoroethylene propylene (FEP).

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It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

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The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims or may include, by way of example and without limitation, one or more of the following claims: